

Conservative Surgical Approach Versus Non-surgical Management for Diabetic Neuropathic Foot Ulcers: a Randomized Trial

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To test the efficacy of surgical treatment of non-infected neuropathic foot ulcers compared to conventional non-surgical management, a group of diabetic outpatients attending our diabetic foot clinic were studied. All patients who came to the clinic for the first time from January to December 1995 inclusive with an uncomplicated neuropathic ulcer were randomized into two groups. Group A received conservative treatment, consisting of relief of weight-bearing, regular dressings; group B underwent surgical excision, eventual debridement or removal of bone segments underlying the lesion and surgical closure. Healing rate, healing time, prevalence of infection, relapse during a 6-month period following intervention and subjective discomfort were assessed. Twenty-four ulcers in 21 patients were treated in group A (17 Type 2 DM/3 Type 1 DM, age 63.24 ± 13.46 yr, duration of diabetes 18.2 ± 8.41 yr, HbA_{1c} $9.5 \pm 3.8\%$) and 22 ulcers in 21 patients in group B (19 Type 2 DM/2 Type 1 DM, age 65.53 ± 9.87 yr, duration of diabetes 16.84 ± 10.61 yr; HbA_{1c} $8.9 \pm 2.2\%$). Healing rate was lower ($79.2\% = 19/24$ ulcers) in group A than in group B ($95.5\% = 21/22$ ulcers; $p < 0.05$), and healing time was longer (128.9 ± 86.60 days vs 46.73 ± 38.94 days; $p < 0.001$). Infective complications occurred significantly more often in group A patients ($3/24$, 12.5% vs $1/22$, 4.5% ; $p < 0.05$), as did relapses of ulcerations (8 vs 3 ; $p < 0.01$). There were only two minor perioperative complications in group B patients. Patients reported a higher degree of satisfaction in group B ($p < 0.01$) as well as lower discomfort ($p < 0.05$) and restrictions ($p < 0.05$). Thus surgical treatment of neuropathic foot ulcers in diabetic patients proved to be an effective approach compared to conventional treatment in terms of healing time, complications, and relapses, and can be safely performed in an outpatient setting. © 1998 John Wiley & Sons, Ltd.

Diabet. Med. 15: 412–417 (1998)

KEY WORDS diabetic neuropathy; foot ulcers; therapy

Received 9 June 1997; revised 20 November 1997; accepted 21 December 1997

Introduction

Peripheral neuropathy is a very common complication in diabetic patients with long duration of disease, and accounts for the majority of foot ulcers, alone or in association with infection or macroangiopathy of the limbs.¹

The typical lesion of neuropathic foot is the neuropathic ulcer, usually located over pressure sites, such as the plantar aspect of the metatarsal heads, or the dorsal surface of the toes. Such lesions are painless and surrounded by hyperkeratosis, which may cover the underlying ulcer completely, with hardened walls and a base which is usually clean and sometimes covered with fibrin or degraded dermal debris.² Non-operative

treatment of the uncomplicated neuropathic ulcer consists of debridement and elimination of hyperkeratosis, regular topical medication and relief using either total contact casts or with orthosis and special shoes.³

The clinical outcome of such treatment depends upon patient compliance, and its duration is related to the dimension and localization of lesions, as well as to the involvement of bony structures in the ulcers.^{4,5}

Recently, some investigators have suggested an alternative way to treat neuropathic foot ulcers by surgery, which includes the excision of ulcer, the debridement or removal of any involved bone and the surgical suture of the wound margins.^{6,7} In order to evaluate the safety and effectiveness of such procedure compared to the conventional management, a study on diabetic neuropathic patients was carried out.

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Patients and Methods

All the patients newly presenting to the foot clinic of our Metabolic Department with an ulcer lasting at least 3 weeks in the calendar year of 1995, underwent clinical screening to select those with non-ischaemic, non-complicated neuropathic ulcers. The study was approved by our local Ethical Committee and carried out according to the guidelines for good clinical practice.

Inclusion criteria were: diabetes mellitus (DM), either Type 1 or Type 2, of at least 5 years' duration; presence of one or more painless foot ulcers with clinical characteristics of neuropathy (symptomatic peripheral neuropathy assessed with the Michigan Neuropathy Screening Instrument (MNSI), absence of ankle reflexes, and abnormal vibration perception threshold (VPT > 25 V) at malleolus and first toe, according to the methodology described by Young *et al.*^{8,9})

Exclusion criteria were: presence of symptomatic claudication or absence of foot pulses, recent keto-acidosis, renal failure as suggested by creatinine higher than $177 \mu\text{mol l}^{-1}$, presence of infection as indicated by perilesional oedema and erythema, or presence of pus, systemic symptoms like fever or leukocytosis. In cases of doubt, a wound swab was sent for bacteriological assessment and no suspicious case was enrolled. Patients with congenital foot deformities or diabetic neuroarthropathy, body mass index (BMI) > 30 kg m^{-2} , clinical history of stroke, cardiac failure, cancer, HIV positivity or history of mental illness were also excluded.

To exclude the possibility of subclinical macroangiopathy, a Doppler study was performed in any case of reduced peripheral pulses. An ankle-brachial pressure index (ABPI) less than 0.9 excluded patients from the study. Osteomyelitis was suspected in any case in which the bone or the joint could be probed through the ulcer. In such cases an X-ray of the foot was examined for signs of osteomyelitis; doubtful cases were excluded.

Lesions were measured, graded according to Wagner's grading scale¹⁰ and photographed with a Polaroid® camera.¹¹ After having obtained their informed consent, patients were randomized into two groups according to a table of randomization: group A received non-operative treatment, consisting of initial debridement and medication of ulcer, relief of weight-bearing regular dressings, and follow-up; group B underwent surgical excision of the ulcer, debridement or removal of bone segments underlying the lesion, necessary, subsequent suture of the skin, and relief of weight-bearing for 4 weeks.

Both treatments were performed on an outpatient basis, in the foot clinic of our metabolic department by trained physicians and personnel. Ulcers in group A patients, after initial debridement of lesions and elimination of surrounding hyperkeratosis, were dressed with saline-moistened sterile gauze and patients were advised to change the dressing every 24 h, helped by a specifically trained relative if necessary. They were given special shoes (Podiabetes®; Buratto, Treviso, Italy) with a custom-

made orthosis to relieve weight from the lesions, and were asked to stand on their feet as little as possible, helping themselves with crutches.¹² They were seen twice a week as outpatients for inspection and control of orthosis. On these occasions lesions were irrigated with an antiseptic solution (povidone iodine 50 % + saline 50 %) and then covered again with saline-moistened gauze. No other medications were used. After healing, patients were provided with a definitive orthosis and moulded shoes. The whole treatment course of group A patients from initial debridement to follow-up visits was performed by physicians and nurses unaware of the participation of patients in the study, and did not differ from the standard protocol of treatment of non-complicated neuropathic ulcerations in our foot clinic.

Group B patients were scheduled for outpatient surgery, after pre-operative evaluation including basal ECG, chest x-ray, blood cell count, plasma chemistry, and virological screening. On the day of surgery, patients had their capillary glucose monitored and controlled with intravenous infusion of 5 % glucose solution with insulin throughout the operation, in order to maintain plasma glucose between 5.5 and 11.1 mmol l^{-1} . Surgical operations were all carried out with local or regional anaesthesia, patients were observed for 3–4 hours after the intervention and then discharged home.¹³

Surgery consisted of the removal of the ulcer through conic ulcerectomy, which removes both the walls and the bottom of the lesion; moreover, in the presence of visible bone segments under the ulcers, or in cases where bone segments might interfere with the closure of the margins of wound, their debridement or removal was performed with scalpels or a rong. To verify the possible presence of osteomyelitis, any resected bone fragments were cultured for microbial or fungal infection. The surgical wound was closed with single stitches and a drain, which was removed after 48 h. The closed wound was covered with sterile gauze and the limb was positioned in slight anti-orthostatic position for 48 h. Then the wounds were treated with antiseptic solution (povidone iodine 50 % + saline 50 %) twice a week. Stitches were removed after 3 weeks. Patients were allowed to walk with crutches and fitted shoes (Podiabetes®; Buratto, Treviso, Italy) for the first week, and 4–6 weeks after the operation they were allowed to walk with orthosis and moulded shoes only.

The following parameters were evaluated: healing rate in a 6-month follow-up period; duration of healing time; prevalence of recurrence and of infective complications. Healing was defined as complete re-epithelization of lesions in group A, and as formation of continuous complete scar for group B. All patients of both groups received foot care education, both during the healing time follow-up visits and at their final visit, when their level of knowledge and skills on foot care was tested.^{14,15} General therapy for group B patients differed from group A in that systemic parenteral therapy with wide-spectrum antibiotics was given 5 days after surgery, according to

the protocols of our hospital for the prophylaxis of nosocomial infection.

At each control visit the patient's logbook for blood glucose monitoring was reviewed and therapy was modified to ensure the best glycaemic control achievable. Once every 2 months glycated haemoglobin (HbA_{1c}) was performed to assess the medium-term control of patients.

At the completion of treatment course, a self-evaluation questionnaire (Appendix 1) was administered to patients of both groups. The questionnaire covered three areas: global level of satisfaction, discomfort during healing time, and limitation of activities. For global level of satisfaction, patients were asked to give a score from 0 to 10, while the other areas were explored through multiple choice questions with four possible answers which ranged from 1 (= least satisfied) to 4 (= most satisfied).

Data, which are expressed as mean \pm standard deviation, were analysed with analysis of variance (ANOVA), equivalent to a *t*-test when used for two groups, chi-square and linear regression tests, using a commercial available software (Statview 512™ on Macintosh SE computer).

Results

Fifty-three of 234 outpatients presenting to our foot clinic for the first time during 1995 fulfilled all inclusion and exclusion criteria (22.6 %), but only 41 were randomized. Of the remaining 12 patients, 6 refused to participate, 5 were unable to comply with the programme, and 1 developed a deep-vein thrombophlebitis in the contralateral limb, which required hospitalization before inclusion in the study.

Of the 41 patients, 20 were randomized to group A, and 21 to group B. Clinical characteristics are reported in Table 1. All lesions were located on pressure sites on the plantar surface or on the medial aspect of the first metatarsal-phalangeal (MTF) joint, on lateral side of the fifth MTF joint, or on the upper site of the interphalangeal joints of the toes. Ulcers were all surrounded or covered by hyperkeratosis and the prevalence according to Wagner scoring system showed no differences between the groups: group A: 67 % grade 1; 33 % grade 2; group B: 64 % grade 1; 36 % grade 2 (Tables 2 and 3).

The clinical course of patients in group B in the post-operative period was satisfactory, except for two minor surgical complications: two stitches broke after accidental trauma in one patient and the drain was removed early by accident in one. All surgical wounds, except for the one that broke, closed by first intention (21/22, 95 %), and only one was complicated with infection during the healing time, although no further surgery was needed to close the wound completely. In no patient were antibiotics continued beyond the 5 days. Group A patients experienced significantly more infective complications than those of group B (3/24, 12.5 % vs 1/22, 4.5 %, $p < 0.05$) and a lower healing rate (19/24, 79 %, $p < 0.05$). Five ulcers in group A failed to heal over the 6 months of follow-up; of these 5 ulcers, 1 worsened and led to a trans-metatarsal amputation for gangrene of the forefoot and general sepsis, despite hospital admission and aggressive intravenous antibiotic administration; 4 healed after 7, 8, 10 and 11 months from the beginning of the study, respectively. The ulcer that failed to heal in group B was one which relapsed; it healed by second intention after 7 months from the beginning of the study.

Healing time of ulcers was significantly shorter in group B than in group A patients (46.73 ± 38.94 vs 128.91 ± 86.60 days, $p < 0.001$), and the difference remained significant after exclusion of those ulcers which healed after the 6-month follow-up period (38.67 ± 9.56 vs 98.11 ± 53.92 days; $p < 0.001$) as shown in Figure 1. Fourteen of 22 ulcers in group B (63.64 %) underwent bone remodelling during surgery, but no difference in healing time was observed between these ulcers (44.87 ± 39.41 days) and those who had no bone remodelling (48.74 ± 18.22 days). We repeated the analysis of healing time between the groups by patient rather than by ulcer, considering, for those patients having more than 1 ulcer, only the worst, since the progress of less serious ulcers may be affected by the treatment of the worst. In this case group A patients showed a healing time of 48.7 ± 36.99 days vs 130.38 ± 90.49 days in group B ($p < 0.001$).

No significant differences in indices of metabolic control were observed between the groups throughout the study period. Recurrence of ulceration in group B over the follow-up were less frequent than for group A (14 % (3/21) vs 41 % (8/19), $p < 0.01$). In group A, 5/8

Table 1. Demographic and clinical features of patients studied

	Group A	Group B	ANOVA
Number of patients (NIDDM/IDDM)	20 (17/3)	21 (19/2)	n.s.
Age (yr)	63.24 ± 13.46	65.53 ± 9.87	n.s.
Duration of diabetes (yr)	18.20 ± 8.41	16.84 ± 10.61	n.s.
Body mass index	27.71 ± 9.43	28.12 ± 13.04	n.s.
Glycated haemoglobin (HbA _{1c} , %)	9.5 ± 3.8	8.9 ± 2.2	n.s.
VPT at first toe (V)	46.13 ± 18.24	48.42 ± 24.19	n.s.
VPT at malleolus (V)	40.08 ± 11.91	43.17 ± 15.22	n.s.

VPT, vibration perception threshold.

Table 2. Characteristics of lesions treated

	Group A	Group B	ANOVA
Number of lesions (lesion/patient)	24 (1.2)	22 (1.05)	—
Maximum diameter (cm)	4.25 ± 2.35	4.32 ± 1.95	n.s.
Maximum depth (cm)	1.58 ± 2.20	1.98 ± 1.07	n.s.
Duration (days)	32.74 ± 19.25	39.43 ± 18.92	n.s.

Table 3. Location of lesions treated

	Group A	Group B
Plantar side (n (%))	16 (67)	13 (59)
Medial first MTF joint (n (%))	5 (21)	5 (23)
Lateral fifth MTF joint (n (%))	2 (8)	4 (18)
Upper side of toes (n (%))	1 (4)	—

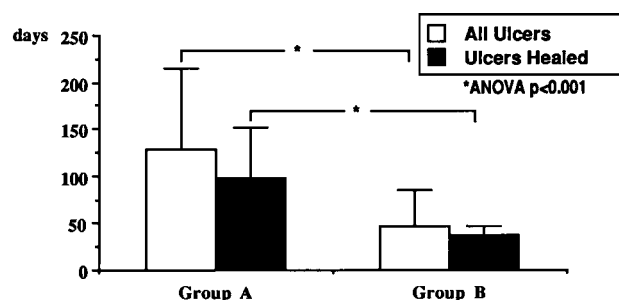
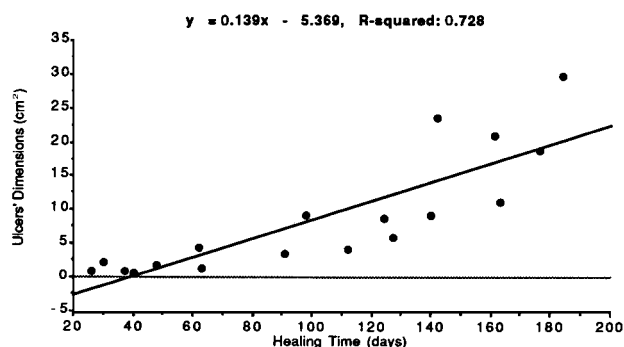


Figure 1. Differences in healing time between groups considering either all ulcerations' clinical course (all ulcers), or only those which actually healed over the 6-month follow-up (ulcers healed)

Figure 2. Correlation between ulcers' dimensions (UD) and healing time in group A patients ($p < 0.001$)

recurrences occurred in the same site of previous ulceration despite the use of an orthosis, while all the recurrences in group B occurred in different sites than that of surgery. In group A patients, a significant correlation ($p < 0.001$) between ulcer dimensions (UD = ulcer maximum diameter \times ulcer maximum depth) and healing time was observed (Figure 2). The same correlation was not observed in group B patients.

As far as the grade of acceptance from patients is concerned, significant differences between the groups

were observed in all the items of the self-administered questionnaire, as shown in Table 4, indicating a higher level of satisfaction for surgical approach than for non-operative treatment.

Discussion

The 'diabetic foot' is one of the most important clinical problems in diabetes care today; about 15 % of diabetic patients are expected to experience foot ulcers during the course of their disease, and foot disease accounts for the majority of hospital inpatient days for diabetic patients.^{16,17} Costs are only partially reckonable, because of the indirect burden of amputations and sequelae, but are much higher than for any other diabetes-related condition, with the possible exception of ischaemic heart disease.^{18,19}

Although foot care is a major issue in diabetes management, there is still no general agreement on the way of treating it, and comparative randomized trials are still lacking.²⁰ Our study demonstrates how a surgical approach to non-complicated neuropathic ulcers is effective in wound healing, shortens healing time, and can be performed on an outpatient basis, thus reducing patient discomfort and health care burdens.

Conventional treatment of neuropathic ulcers is mainly based on strategies to relieve weight bearing and prevention of infection with regular dressings.²¹ Although generally effective, the outcomes of this approach depend on variables such as ulcer size, duration and position, patient compliance, frequency of dressing changes, and occurrence of systemic infections. The surgical solution is based on three points: debridement of chronic granulation tissue; closure with fresh tissue; and decrease of pressure under the ulcer. Perilesional chronic inflammatory reactions and the formation of 'fibrin cuffs' around the sub-papillary plexus obstruct the diffusion of blood cells, cytokines and growth factors, necessary to wound healing.²² Surgical elimination of the walls and the base of the ulcer re-establishes a condition which is much

Table 4. Results of self-reported patients' satisfaction

	Group A	Group B	ANOVA
Global satisfaction (0–10)	5.4 ± 3.1	7.9 ± 3.8	$p < 0.01$
Discomfort (1–4)	2.9 ± 1.8	1.7 ± 1.2	$p < 0.05$
Limitations (1–4)	3.6 ± 2.1	1.4 ± 1.1	$p < 0.01$

more mobile, transforming a chronic ulcer into a fresh wound, with the expected clinical course of other surgical wounds. In the case of neuropathic foot ulcers, which are generally determined by inappropriate pressure loads on foot regions with underlying bone, their debridement or removal can significantly reduce the pressure at that particular point, making it possible to close the elliptical incision without tension, or the necessity of plastic surgery.⁷

The general therapy of group B patients differed from those of group A in the administration of parenteral antibiotics for 5 days after surgery. However, we do not think that this was a major factor in the improved prognosis of group B as the therapy was only a prophylaxis against post-operative infections, and no patient showed signs of infection before the surgery.

Although the majority of neuropathic foot ulcers in this study healed with the conventional non-surgical treatment, the longer healing time and the higher incidence of infections in this group of patients make it less convenient and safe than the surgical approach.²³ Previous reports have compared foot care outcomes in different centres and found that, despite superimposable success rates, a more surgically-oriented approach was associated with shorter healing time. This is the first time that surgical and conventional treatments have been compared in a prospective randomized study.²⁴ Our data show that, when applied in a carefully selected population, the conservative surgical approach not only shortens healing time, but also improves healing rates.

One possible contributor to the success of therapy in group B is the reduced need for compliance with self care. Analysis of associations of complications in group A patients, identified non-compliance (refusal to wear healing shoes, missing of control visits) or errors (i.e. using alcohol for medications, walking barefoot in seawater), while surgical procedures reduced the necessity of patients' compliance by diminishing their involvement in the management of lesions; all that patients were requested to do was to rest for 1 week and then to walk with crutches for 3 weeks, non-weight bearing on the operated foot. Non-compliance in the surgery group was limited to missing the control visits: two patients missed one control and one missed two controls. In all cases patients were contacted by phone and visits were performed with a maximum of 2 days of delay. Both the complications in group B followed accidents of procedure during control visits or dressings.

Although total contact casts are now considered the first-choice treatment for neuropathic ulcers, with rates of healing and healing time duration roughly superimposable to those we achieved, we think that surgery deserves a place among the strategies for management of ulcers, especially in those cases in which bony prominences create obstacles to healing.^{25,26} Total-contact casts have some contraindications and adverse effects, like phlebotasis and secondary abrasions, as well as muscular atrophy and fungal infections.^{27,28} Surgical technique has no

absolute contraindications in well-vascularized patients and, as we observed, the prevalence of complications can be lower than in conventional treated patients. Recurrence of ulceration was lower in group B than in group A patients, and although a 6-month follow-up period may be too short to evaluate the real outcome in the long term, it is noticeable that not one of the group B patients had a re-ulceration in the place where the previous one was located. It is possible that bone resection creates new sites subjected to elevated pressures, which are then prone to develop new ulcerations, but even so the probability of new ulceration is less than the risk of a recurrence in group A patients.

Finally, in our study, patients' self-reported level of satisfaction was higher in the surgical treated group than in the conventional treated one, and the patients reported significantly less discomfort than those of the latter one, thus confirming their appreciation of the surgical approach.

We conclude that conservative surgical treatment of non-complicated neuropathic foot ulcers in diabetic patients is an effective approach, and compares favourably with conventional treatment in terms of healing time, complications and relapses. It can be safely performed in a dedicated setting. In our opinion, ulcer excision and bone remodelling should be considered as an early alternative in case of neuropathic ulcers.

Acknowledgement

The authors are grateful to L. Benzi for reviewing the manuscript and for the criticism.

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Appendix 1. Self-administered questionnaire for the evaluation of patients' satisfaction

1. In a range from 0 to 10 (0 = no satisfaction at all, 10 = maximally satisfied), your level of satisfaction scores:
2. Your general feeling of discomfort over the healing time was
 1. absent
 2. tolerable
 3. scarcely tolerable
 4. absolutely unbearable
3. The limitations in your everyday life habits were:
 1. few, and not heavy
 2. few, but heavy
 3. many, but not heavy
 4. many and heavy